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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/069,847	04/30/1998	MYUN KI HAN	010091-035	3819

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT

PAPER NUMBER

1634

24

DATE MAILED: 08/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/069,847

Applicant(s)

HAN ET AL.

Examiner

Jeffrey Fredman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 66-100 and 102-108 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 66-100 is/are allowed.
- 6) ☒ Claim(s) 102-108 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Status***

1. The current applicant was part of Interference 104,670. This interference was decided by the BPAI, which noted that there was no interference in fact. The BPAI did note, however, that claims 102-108 should be subject to a prior art 102 rejection over the Lee reference. That rejection follows.

### ***Allowable Subject Matter***

2. Claims 66-100 remain allowed.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 102, 103 and 105-108 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al (Nucleic Acids Research (1993) 21(16):3761-3766).

Lee teaches a method for continuously detecting a cleavage reaction by a fluorometric assay (see abstract and figure 1) comprising:

(i) producing a double stranded nucleic acid sequence that comprises a fluorescent donor and acceptor pair, where said fluorescent donor and acceptor are positioned on said double stranded nucleic sequence such that fluorescence is quenched by the transfer of donor fluorescence to the acceptor (see page 3762, figure 1),

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(ii) contacting said double stranded nucleic acid sequence with an enzyme that catalyzes a cleavage reaction that results in separation of the donor and acceptor pair (see page 3762, figure 1 and column 2),

(iii) continuously monitoring the change in fluorescence intensity as said cleavage reaction proceeds (see page 3765, figure 6).

With regard to claim 103, the donor and acceptor are in the same strand of the double stranded sequence (see page 3762, figure 1).

With regard to claim 105, Fam and TMR are used (see page 3762, figure 2).

With regard to claims 106 and 107, the method occurs during PCR amplification (see page 3762, column 2).

With regard to claim 108, the nucleic acid is a DNA sequence (see page 3762, column 2).

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 104 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (Nucleic Acids Research (1993) 21(16):3761-3766) in view of Parkhurst.

Lee teaches a method for continuously detecting a cleavage reaction by a fluorometric assay (see abstract and figure 1) comprising:

- (i) producing a double stranded nucleic acid sequence that comprises a fluorescent donor and acceptor pair, where said fluorescent donor and acceptor are positioned on said double stranded nucleic sequence such that fluorescence is quenched by the transfer of donor fluorescence to the acceptor (see page 3762, figure 1),
- (ii) contacting said double stranded nucleic acid sequence with an enzyme that catalyzes a cleavage reaction that results in separation of the donor and acceptor pair (see page 3762, figure 1 and column 2),
- (iii) continuously monitoring the change in fluorescence intensity as said cleavage reaction proceeds (see page 3765, figure 6).

With regard to claim 103, the donor and acceptor are in the same strand of the double stranded sequence (see page 3762, figure 1).

With regard to claim 105, Fam and TMR are used (see page 3762, figure 2).

With regard to claims 106 and 107, the method occurs during PCR amplification (see page 3762, column 2).

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With regard to claim 108, the nucleic acid is a DNA sequence (see page 3762, column 2).

Lee does not expressly teach placement of the labels on alternate strands.

Parkhurst (Biochemistry) teaches a DNA probe labeled at the 3' and 5' ends with fluorescein and rhodamine respectively which probe is complementary to the target nucleic acid, said probe nucleic acid is shown and stated to alternate between a folded and unfolded configuration (page 285, abstract and page 292, column 1),

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to place the labels on alternate strands since Parkhurst exemplifies this as an alternate configuration which permits fluorescent quenching.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

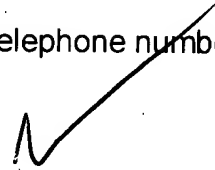
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jeffrey Fredman  
Primary Examiner  
Art Unit 1634

July 23, 2003